

Remarks

By the foregoing Amendment, claims 10-12 are cancelled, and new claims 50-68 are presented. Entry of the Amendment, and favorable consideration thereof is earnestly requested.

The invention relates to pharmaceutical compositions comprising agents such as Etx, EtxB, mutants and derivatives thereof, and antibody agents having GM1 binding activity. The compositions may be combined with one or more pharmaceutically acceptable carrier, diluent, excipient or adjuvant (and any combination of these). The composition may further be adapted to include an antigen, wherein the agent and the antigen are not so linked to form a single active agent. The compositions are particularly useful in treating autoimmune disease such as diabetes, arthritis, and multiple sclerosis.

Claims 10-12 were rejected as anticipated by Yankelvich. The examiner has taken the position that Ctx-B was used in an aqueous solution, which is pharmaceutically acceptable. The claims as amended do not relate to Ctx-B. Moreover, nowhere does Yankelvich suggest modifying the active agent, to include Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, accordingly the claimed invention is not obvious.

Claims 10-12 were further rejected as anticipated by Holmgren in view of Francis and Kaper. New claims 50, 65-68 require, among other things, specific agents listed in Markush format. Nowhere does Holmgren teach or suggest the inclusion of such agents. In fact, Holmgren specifically teaches away from the present invention for Holmgren is directed to an immunological tolerance-inducing agent comprising a mucosa-binding molecule linked to a specific tolerogen. See, *i.e.* page 8, lines 34-36. The claimed agents are not linked to a tolerogen. Therefore, new claims 50, 65-68 are not anticipated by Holmgren.

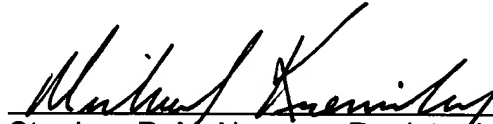
The claimed composition is not shown in any of the art of record. Consideration of new claims 50-68 is requested. No new matter has been added.

Page 7
Serial No. 09/867,914
July 25, 2003

It is respectfully submitted that new claims 50-68, all of the claims remaining in the application, are in order for allowance, and early notice to that effect is respectfully requested. If the Examiner has any questions about this communication he is invited to call Michael Krenicky at (203) 324-6155 to discuss.

Applicant believes that the number of claims paid for at the time of filing exceeds the cost of the claims added herein. Accordingly it is believed that no additional claim fees are due.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael W. Krenicky", is written over a horizontal line.

Stephen P. McNamara, Registration No. 32,745
Michael W. Krenicky, Registration No. 45,411
Attorneys for Applicants
ST.ONGE STEWARD JOHNSTON & REENS LLC
986 Bedford Street
Stamford, CT 06905-5619
203 324-6155